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UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

EASTERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

CALIFORNIA STEM CELL TREATMENT CENTER, INC., *et al.*

Defendants.

No. 5:18-CV-01005-JBG-KKx

PLAINTIFF'S [PROPOSED] FINDINGS OF FACT AND CONCLUSIONS OF LAW

Trial Date: July 28, 2020

Honorable Jesus G. Bernal
United States District Judge

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I. PLAINTIFF'S CLAIMS

1. Defendants violate 21 U.S.C. § 331(k) by causing the adulteration of CSCTC products within the meaning of 21 U.S.C. § 351(a)(2)(B), while they are held for sale after shipment of one or more of their components in interstate commerce.

2. Defendants violate 21 U.S.C. § 331(k) by causing the misbranding of CSCTC products within the meaning of 21 U.S.C. §§ 352(f)(1), 352(j), and 353(b)(4), while they are held for sale after shipment of one or more of their components in interstate commerce.

3. Defendants CSCTC, Berman, and Lander violate 21 U.S.C. § 331(c) by receiving drugs that are misbranded within the meaning of 21 U.S.C. §§ 352(f)(1) and 353(b)(4) in interstate commerce and delivering or proffering for delivery such drugs for pay or otherwise.

II. PROCEDURAL HISTORY

1. This case is an action for civil injunctive relief filed by Plaintiff, the United States of America, on behalf of the U.S. Food and Drug Administration ("FDA"). The Government brings this statutory injunction proceeding pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 332(a), to enjoin Defendants, including California Stem Cell Treatment Center, Inc. ("CSCTC"), from violating the FDCA, including its adulteration and misbranding prohibitions.

2. The Government filed its Complaint for Permanent Injunction on May 9, 2018. Defendants filed their Answer to the Complaint on July 17, 2018. (ECF No. 27).

3. On July 8, 2019, the Government moved for summary judgment, on the grounds that Defendants violate the FDCA by, among other things, causing the adulteration and misbranding of drugs. (ECF No. 45).

4. On January 27, 2020, the Court denied the Government's summary judgment motion and set the matter for trial ("SMJ Order"). (ECF No. 84). The Court ruled that the "central dispute" at trial would be whether the "same surgical procedure exception exempts the SVF Process from FDA oversight." (*Id.* at 10). The Court specifically

identified just one issue of fact for trial, namely "whether the SVF Procedure alters the SVF cells." (*Id.* at 13).

5. On March 19, 2020, the Government filed a Motion for Clarification of the Scope of Trial With Respect to the FDCA. (ECF No. 90). The motion sought the Court's clarification as to whether the Government should *(a)* limit its trial evidence to the single issue of fact identified in the SMJ Order or *(b)* also present evidence to prove the claims in its Complaint that Defendants violate the FDCA by causing the adulteration and misbranding of their drugs, and by receiving and delivering misbranded drugs, in violation of 21 U.S.C. §§ 331(k) and (c).

6. On April 14, 2020, the Court ruled on the Government's Motion for Clarification. (ECF No 102). The Court confirmed that this case "concerns . . . alleged violations of the FDCA" on which the Court had "made no ultimate findings of fact" in its SMJ Order. (*Id.* at 1). The Court ordered the Government to produce evidence at trial to establish any elements where it carries the burden. (*Id.* at 2). Defendants were likewise ordered to produce evidence at trial where they carry the burden. (*Id.*).

7. On April 28, 2020, the Court scheduled the case for bench trial on July 28, 2020. (ECF No. 114).

III. FINDINGS OF FACT

A. The Defendants and their CSCTC products

1. Defendant CSCTC is a California professional corporation founded in 2010, with its principal place of business located at 72-780 Country Club Drive, Suite 301, Rancho Mirage, California 92270 ("CSCTC Rancho Mirage"), and a second establishment located at 120 South Spalding Drive, Suite 300, Beverly Hills, California 90212 ("CSCTC Beverly Hills"), within the jurisdiction of this Court.

2. CSCTC manufactures, or has caused to be manufactured, several adipose (fat) derived products ("CSCTC products"), including the following: (1) a product containing what is referred to as "stromal vascular fraction" (the "SVF product") which is manufactured from a patient's adipose tissue; (2) a product that combines SVF and

Vaccinia Vaccine, Live (the "SVF/Vaccinia product"); and (3) a product containing SVF that has been expanded in culture for CSCTC by a third party (the "Expanded SVF product"). [1]

3. Defendant Elliot B. Lander, M.D., a board-certified urologist and surgeon, is the co-owner and Co-Medical Director of CSCTC. He is the most responsible individual at CSCTC Rancho Mirage and performs his duties at CSCTC Rancho Mirage, within the jurisdiction of this Court. He manages all firm employees at CSCTC Rancho Mirage, where his activities include recovering adipose tissue from patients and manufacturing CSCTC products. Dr. Lander is the co-owner and Co-Medical Director of Defendant Cell Surgical Network ("CSN"). He is also the co-owner of Cells On Ice, Inc., which has assisted in the recovery of adipose tissue sent outside of the State of California for production into the Expanded SVF product.

4. Defendant Mark Berman, M.D., a board-certified cosmetic surgeon, is the co-owner and Co-Medical Director of CSCTC. He performs his duties at the CSCTC Beverly Hills facility, within the jurisdiction of this Court. He is the most responsible individual at CSCTC Beverly Hills, where his activities include recovering adipose tissue from patients and manufacturing CSCTC products. Dr. Berman is the co-owner and Co-Medical Director of Defendant CSN and co-owner of Cells On Ice, Inc.

5. Defendant CSN is a California corporation founded by Defendants Berman and Lander in 2012 that is registered to do business at 72-780 Country Club Drive, Suite 301, Rancho Mirage, California 92270, the same address as CSCTC Rancho Mirage, within the jurisdiction of this Court. CSN operates a one-employee warehouse at 73700

[1] Although Defendants insist that they perform "procedures" and do not manufacture products, Defendants have published several medical articles wherein they confirm that the SVF that they administer to patients is a biological product. *See* Elliot B. Lander et al., *Personal cell therapy for interstitial cystitis with autologous stromal vascular fraction stem cells*, 11 Therapeutic Advances Urology 1, 5 (2019) ("SVF is an autologous biologic product derived in surgery from the enzymatic digestion of adipose tissue, which is split into its fat fraction (adipocytes) and stromal and vascular fractions (containing regenerative cells)").

Dinah Shore Drive, Suite 301, Palm Desert, California 92211, within the jurisdiction of this Court, from which equipment and supplies are shipped to CSN affiliates.

6. CSCTC products are intended for autologous use, which refers to the "implantation, transplantation, infusion, or transfer of human cells or tissue back into the individual from whom the cells or tissue were recovered." See 21 C.F.R. § 1271.3(a).

7. CSCTC products are administered to patients to purportedly treat neurological, autoimmune, orthopedic, and degenerative medical conditions and/or diseases, including, but not limited to, cancer, arthritis, stroke, amyotrophic lateral sclerosis ("ALS"), multiple sclerosis ("MS"), macular degeneration, Parkinson's disease, and chronic obstructive pulmonary disease ("COPD").

8. CSCTC products are administered to patients using a variety of methods, including intravenously; injection into specific areas of the body, including an area around the brain; and via a nebulizer. CSCTC products are administered at CSCTC Rancho Mirage and CSCTC Beverly Hills, and at other locations such as a radiologist's office in Indian Wells, California.

9. Many patients pay thousands of dollars to receive a single dose of the CSCTC product, and some patients pay much more to receive multiple treatments. Defendants have referred to this practice as "patient-funded research."

B. Defendants cause the disruption and digestion of adipose tissue removed from patients to manufacture their cellular-based CSCTC products

10. Production of CSCTC products involves the recovery of adipose tissue from patients at the offices of CSCTC Rancho Mirage and CSCTC Beverly Hills. The tissue recovery is accomplished by a mini-liposuction procedure, whereby a cannula is used to recover adipose tissue through an incision commonly made in the patient's posterior flank.

11. Defendants subject the recovered adipose tissue to numerous steps through which many components of the tissue are broken down and discarded. The process involves the addition of a collagenase solution to isolate cell components through enzymatic digestion. It also includes an incubation period, several washing steps using

5% Dextrose in Lactated Ringer's Injection, centrifugation, and filtration. The manufacture of the CSCTC products employs various types of equipment, including, but not limited to, a specialized SVF processing device identified as the "Time Machine," syringes, plungers, stoppers, adapters, and a filter.

12. Adipose tissue is typically defined as a connective tissue composed of predominantly adipocyte cells that are surrounded by an organized extracellular matrix and interspersed small blood vessels, divided into lobes and lobules by connective tissue septa.

13. The extracellular matrix that adipose tissue contains is comprised of various types of fibrous collagen and resembles the walls of a three-dimensional foam, with each adipocyte occupying a pore cavity of the foam. The extracellular matrix surrounding the adipocytes is also described as a "reinforced basement membrane." Other than adipocytes, adipose tissue also contains some other cells, including preadipocytes, fibroblasts, vascular endothelial cells, and macrophages.

14. Because adipose tissue mainly provides cushioning and support to the body, such as the skin and internal organs, it is a structural tissue. In addition to providing cushioning and support, adipose tissue performs other functions in the body, including storing energy in the form of lipids, and insulating the body.

15. One characteristic of adipose tissue is its ability to hold its shape and form.

16. Defendants' processing of adipose tissue to manufacture the CSCTC products alters the tissue's physical properties.

17. Defendants' processing of adipose tissue alters the original relevant characteristics of the adipose tissue relating to the tissue's utility for reconstruction, repair, or replacement.

18. Defendants' processing of adipose tissue to manufacture the CSCTC products involves removing adipocytes from the adipose tissue.

19. Defendants' processing of adipose tissue to manufacture the CSCTC products also removes the extracellular matrix and interspersed small blood vessels from

adipose tissue.

20. After Defendants process adipose tissue into SVF, the SVF product no longer retains the original form of adipose tissue whereby adipocytes are surrounded by an extracellular matrix and interspersed small blood vessels.

21. SVF is a liquified mixture of cells and cell debris that does not contain an extracellular matrix and does not contain adipocytes.

22. The group of select isolated cells that comprise SVF does not occur naturally in the body. The cells that comprise SVF are brought together only through elimination of the organized adipose tissue architecture and dismantling of organized multicellular structures (e.g., blood vessels).

23. SVF is not intended to perform the same basic functions of the adipose tissue recovered from Defendants' patients.

24. Defendants do not implant adipose tissue into patients.

25. Defendants' preparation and administration of the CSCTC products use one or more components shipped in interstate commerce from places outside the State of California. Components received from outside California include, for example, 0.9% Sodium Chloride Injection, USP and 5% Dextrose in Lactated Ringer's Injection, both of which originate outside the state of California. Defendants' manufacturing process also involves their use of a collagenase product made in Indiana.

26. Defendants use a collagenase product (i.e., an enzyme mixture that degrades collagen) made in Indiana to prepare their SVF product.

27. Defendants use the collagenase product to disrupt and digest the reinforced basement membrane to dissociate the cellular components of the adipose tissue.

28. Safety concerns reasonably arise when an enzyme is used to disrupt and digest adipose tissue to isolate cells that are later administered to patients. The safety risks of enzymes used to breakdown adipose tissue were recognized, for example, in *Cytori Therapeutics v. FDA*, 715 F.3d 922 (D.C. Cir. 2013). In *Cytori*, the petitioner challenged FDA's determination that its medical devices, which isolated cells from fat tissue, were

not substantially equivalent to predicate devices that isolated cells from blood and bone marrow. In determining that FDA's determination was reasonable, the Court highlighted FDA's concern that Cytori's devices used an enzyme (Celase) "to aid the separation of stem cells from fat tissue," and that Celase had only been approved by FDA to liquefy fat waste after liposuction for purposes of disposal. 715 F.3d at 927. The Court explained that FDA "reasonably raised concerns" about the enzyme's impact on isolated cells that "might be reintroduced into the human body." *Id*. at 927-928.

29. Defendants do not confirm that the collagenase enzyme used during production has been eliminated before the CSCTC products are administered to patients.

30. Certificates of Analysis received by Defendants indicate that the enzyme used during production is to be used "for in vivo use only" as opposed to surgical use.

31. Defendants administer certain of their CSCTC products—such as their SVF product—on the same day that the patient's adipose tissue is removed. For intravenous administration, the SVF is added to a 100ml bag of 0.9% Sodium Chloride (NaCl) solution and given to the patient through an intravenous drip. This combination of SVF and Sodium Chloride solution constitutes the "SVF Product."

32. Labeling on the CSCTC products lacks indications for use, dosages, routes of administration, and side effects. The labeling on the CSCTC products does not identify them as "Rx only."

C. Defendants' manufacturing process for the CSCTC products alters the SVF cells[2]

33. In their Responses to Plaintiff's First Set of Interrogatories, Defendants acknowledged that they "obtain[] the patient's own cells from his/her adipose tissue."

34. Briefly, SVF isolation by Defendants begins with aspiration and recovery of

[2] The Government does not concede that the alteration of the SVF cells specifically is relevant to an analysis of the Same Surgical Procedure exception set forth in 21 C.F.R. § 1271.15(b). The Government respectfully maintains that the section 1271.15(b) analysis turns on whether "such HCT/P"—here, adipose tissue—is returned to the patient, not whether cells isolated from that tissue are altered. In its SMJ Order, the Court specifically noted that "whether the SVF Procedure alters the SVF cells" would be relevant at trial. (ECF No. 84 at 13). The Government proffers factual findings relating to SVF cell alteration solely to address this issue identified by the Court.

approximately 50 mL of adipose tissue from the individual. The aspirated adipose tissue is centrifuged to remove blood cells, loose lipids, and local anesthetic solution. Defendants then add an enzyme mixture that degrades collagen, among other proteins, to the adipose tissue in order to disrupt and digest the reinforced basement membrane to dissociate the cellular components of the adipose tissue. The digested tissue undergoes a series of processing steps including washing and centrifugation, to separate non-adipocyte cellular and digested structural components of the tissue from dissociated adipocytes and free lipids. Defendants next employ filtration whereby the non-adipocytic cells (i.e., SVF) are isolated from the digested structural components of the adipose tissue by pushing the mixture through a filter where the pore size effectively only allows cells below a certain diameter to pass, i.e., the digested structural components of the adipose tissue are filtered out. What remains, according to Defendants, is the isolated SVF suspended in a solution to yield the final CSCTC SVF product of approximately 5-10 mL.

35. The enzymatic digestion and other processing steps Defendants undertake to isolate the SVF cells from the adipose tissue alter the physical and biological characteristics of the SVF cells in the CSCTC products. Physical characteristics of cells include shape and physical form (i.e., morphology) and cell surface receptor expression. Biological characteristics of cells include activation state, differentiation and proliferation potential, and metabolic activity.

36. When tissue is enzymatically digested, cells that are necessarily adhered to the extracellular matrix and normally assume a flat, spread and protruded morphology in their native state change to a contracted, spherical form. Consequently, the inner cytoskeleton of the cells that is responsible for providing mechanical support and for keeping internal cellular structures organized loses tension and extensively rearranges. Enzymatic digestion of tissue also cleaves proteins on the surface of the cell, including cell surface receptors that are critical in mediating cell signaling among other key aspects of cellular function and behavior.

37. The manufacture of CSCTC's SVF Product involves the dissociation of the

extracellular matrix through enzymatic digestion and, consequently, changes in the activation state of cells in the resulting cell suspension. This means the main attributes of cells (e.g., cell surface receptor expression) and their behavior (e.g., signaling activity) change in response to a stimulus. Depending on the nature of the response(s) to a stimulus, cells change their metabolic activity. Upon activation, cells generally increase their metabolic activity to meet the demands of stimulation.

38. A report submitted by Defendants' expert, Dr. Lola M. Reid, states that "dissociation of the extracellular matrix with collagenase results in cell suspensions with activation of especially early lineage state cells and their paracrine signaling." Processing that affects the activation state and signaling activity of cells alters cellular processes, their metabolic activity, and the cells' capacity to mediate the behavior of other cells in the case of paracrine signaling. Thus, the *ex vivo* enzymatic processing that dissociates the extracellular matrix of adipose tissue in CSCTC's manufacture of the SVF Product alters the relevant biological characteristics of the cells derived from the adipose tissue.

39. Enzymatic digestion of the structural components of adipose tissue (e.g., extracellular matrix and blood vessels) also disrupts critical cell adhesion to other cells and particularly to the extracellular matrix. Cell adhesion to other cells and to the extracellular matrix governs how cells responds to their environment and, consequently, cell behavior.

40. Anchorage-dependent cells, such as the stromal and vascular cells that comprise SVF, will not grow, proliferate, or differentiate—and some cell types will not survive—unless they are attached to extracellular matrix. Thus, the *ex vivo* enzymatic processing that eliminates cell attachment alters the proliferation and differentiation potential of the cells derived from the adipose tissue.

41. When the extracellular matrix is digested, and the dissociated cells are filtered, key cellular functions of these cells, including but not limited to cell adhesion, cell-cell signaling, and cell-extracellular matrix signaling, are effectively abolished. As a result, the different cell types are removed from their organized microenvironment and

cannot mediate their specialized roles.

42. For example, adipose tissue contains endothelial cells which are organized through specialized cell-cell adhesions to protectively line the inside of blood vessels and allow white blood cells to move into (i.e., extravasate to) the target surrounding tissue. As single free-floating cells in SVF due to processing, they no longer can mediate these functions.

43. Defendants have not demonstrated that the processing they undertake does not alter the cells contained in the CSCTC products they administer to their patients.

D. Defendants manufactured certain CSCTC products containing a live virus

44. Defendants have manufactured an SVF/Vaccinia product involving a combination of SVF and Vaccinia Vaccine, Live. Vaccinia Vaccine, Live, is also known by its proprietary name ACAM2000. ACAM2000 is an FDA-approved biological product for active immunization against smallpox disease for persons determined to be at high risk for smallpox infection. The vaccine's labeling is required to display a "black box warning" designed to call attention to serious or life-threatening product risk, including swelling of the heart tissues, brain, or spinal cord. See 21 C.F.R. § 201.57(c)(l).

45. Defendants have promoted and used their SVF/Vaccinia product as a purported treatment for a variety of advanced-stage cancers. The SVF/Vaccinia product was administered to patients intravenously or directly into patients' tumors. The SVF/Vaccinia product contained amounts of the vaccine that greatly exceeded the vaccine's labeled dose.

46. At her deposition, Defendants' expert witness, Lola M. Reid, Ph.D., conceded that adding a vaccine to SVF would make her "nervous" because "there are many things that can happen."

47. The Vaccinia Vaccine, Live, that Defendants used to manufacture their SVF/Vaccinia product was shipped in interstate commerce from Georgia.

E. Defendants have received certain CSCTC products manufactured outside California

48. To manufacture their Expanded SVF product, Defendants sent recovered adipose tissue to a firm located outside of the State of California. The outside firm used enzymes and laboratory equipment, including a centrifuge and a filter, to produce SVF from the adipose tissue. It then cultured the SVF to expand it to a higher cell density. The Expanded SVF products subsequently were returned in interstate commerce to CSCTC Rancho Mirage and CSCTC Beverly Hills and administered to patients.

F. Defendants control a network of affiliates that also administer their SVF products

49. Defendant CSN, which is co-owned by Defendants Berman and Lander, approves doctors to become affiliates or licensees. CSN affiliates are required "to complete training" by the Defendants regarding the manufacture of the SVF product. Once approved for inclusion in the CSN network, CSN affiliates purchase supplies from CSN to make the CSCTC SVF products. To maintain their status, CSN affiliates must share research data with Defendants and other CSN affiliates.

50. CSN affiliates are "required to comply with" CSN's "Guidelines for Affiliates," which states that an affiliate "must" "reasonably follow price guidelines to avoid competition for patient enrollment within the network," register patients into the CSN Database, and use standardized forms, including specific consent forms for patient care and data collection.

51. CSN's "Guidelines for Affiliates" describes that affiliates have limited permission to use various trademarks and logos, including logos for California Stem Cell Treatment Center, CSCTC, and Cell Surgical Network.

52. Defendant Lander asserted that CSN affiliate doctors have administered SVF products to more than 6,000 patients. Defendants Berman and Lander refer to CSN affiliate clinics as "sub-investigators."

G. Defendants claim their CSCTC products treat cancer and other serious diseases and conditions

53. A CSN website, http://stemcellrevolution.com/about-us/faqs/, answers the question "Can stem cells treat cancer?" and explains that CSN is involved in "cutting edge clinical trials using stem cells to carry cancer-killing biologic agents deep into cancer tissue that has not responded to conventional therapy."

54. A CSN website, https://stemcellrevolution.com/currently-studying, lists more than 30 diseases or conditions that CSN is "currently studying," including MS, ALS, cardiomyopathy, lupus, and macular degeneration.

55. A CSCTC brochure entitled "Adipose Stem Cell Therapy and You" that Defendants provided to prospective patients markets "a solution rich with your own stem cells" that "can be deployed to treat a number of degenerative conditions and diseases." The brochure notes that there have been "reports of improvements with MS, Muscular Dystrophy, Parkinson's, ALS, and stroke."

56. A videotaped interview of Defendant Lander, available at https://www.youtube.com/watch?v=otushsFxkzw, promotes SVF "for cancer therapies," arthritis, heart disease, lung disease and interstitial cystitis, and "brain conditions [by] injecting the cells directly into the brain."

57. A video by Defendant Berman, available at https://www.youtube.com/watch?v=SVVQrosn0gc, describes the SVF product as "magical cells in your fat" and "liquid magic" used to treat "COPD, heart disease, neurodegenerative problems, . . . interstitial cystitis . . . Peyronie's and erectile dysfunction."

58. A CSN FAQ video, available at https://www.youtube.com/watch?v=fWi_UzX-i_A, describes CSN's "investigative protocols for studying . . . arthritis, neurologic disease, urologic disease" and how the same cells are "capable of fixing anything."

H. Defendants' CSCTC products lack FDA approval for any such uses

59. None of the CSCTC products have been licensed or approved by the United States Food and Drug Administration ("FDA") for any use.

60. There are not now, nor have there ever been, any approved new drug applications ("NDAs") filed with FDA pursuant to 21 U.S.C. § 355(b) or (j) for the CSCTC products. There are not now, nor have there ever been, any approved biologics license applications ("BLAs") filed with FDA pursuant to 42 U.S.C. § 262 for the CSCTC products.

61. Although Defendants have had discussions with FDA concerning their desire to study the SVF/Vaccinia product pursuant to an Investigational New Drug Application ("IND") under 21 U.S.C. § 355(i), no IND is currently in effect for that product or for any of Defendants' other CSCTC products.

62. There have been no adequate and well-controlled studies performed with the Defendants' CSCTC products demonstrating that they are safe or effective for any indication (i.e., for any intended use).

63. Defendants' CSCTC products are not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling.

64. Medical expertise, licensure, and appropriate subspecialty training are required to diagnose the diseases and condition(s) that Defendants purport to treat and to determine the appropriate therapeutic intervention(s) for diseases and conditions for which the CSCTC products are used.

65. Medical expertise, licensure, and/or appropriate training are required to administer the CSCTC products through the intended parenteral routes of administration.

66. Autologous biological products may be created for individual patients using the patients' own cells and FDA routinely reviews applications concerning such products.

I. Inspections show Defendants and the CSCTC products violate the law

67. FDA inspected CSCTC Rancho Mirage from July 17-26, 2017, and CSCTC Beverly Hills from July 21-27, 2017. At the close of the inspections, FDA investigators issued lists of inspectional observations ("Form FDA 483s") to Defendants Berman and

Lander.

68. The July 2017 inspections showed that the manner in which Defendants manufacture the CSCTC products did not comply with current Good Manufacturing Practice regulations for drugs ("CGMP"). The 2017 inspections showed that the methods, facilities, and controls Defendants used in manufacturing, processing, packing, and holding the CSCTC products did not conform to, and are not operated or administered in conformity with, CGMP. See 21 U.S.C. § 351(a)(2)(B) and 21 C.F.R. Parts 210-211; see also 21 C.F.R. Parts 600-680 (setting forth additional standards and manufacturing requirements applicable to biological products).

69. The July 2017 inspections showed that Defendants failed to establish and follow appropriate written procedures designed to prevent microbiological contamination of drug products purporting to be sterile, in violation of 21 C.F.R. § 211.113(b), because they did not prepare the CSCTC products under aseptic conditions, nor did they validate their manufacturing process to demonstrate that it was aseptic.

70. For example, the FDA investigators found that at both the CSCTC Rancho Mirage and Beverly Hills facilities, Defendants cleaned the "surgery" rooms where adipose tissue was recovered from patients only three times a week and performed no environmental monitoring to demonstrate that such cleaning was acceptable for aseptic manufacturing.

71. FDA investigators at the CSCTC Rancho Mirage facility observed that Defendants allowed a patient to wear street clothes in the "surgery" room, and that Defendants left the door to the "surgery" room open with a floor fan blowing air through the doorway from elsewhere in the building while recovering adipose tissue and manufacturing the CSCTC products.

72. The July 2017 inspections also showed that Defendants did not subject CSCTC products to appropriate laboratory testing to ensure that they were free of objectionable microorganisms, as required by 21 C.F.R. § 211.165(b), to ensure the safety of those products. For example, Defendants performed no sterility or endotoxin testing

on batches of autologous SVF product at their CSCTC Rancho Mirage and Beverly Hills facilities at the time of FDA's 2017 inspections. Additionally, although CSCTC's SVF/Vaccinia Vaccine Safety Protocol stated that "Aliquots of each cell suspension will be set aside for endotoxin testing and sterility testing . . . [and] SVF will only be released for injection after confirmation of endotoxin assay results of level of EU less than or equal to 5EU/kg/hr and negative gram stain results," Defendants did not follow these guidelines at either CSCTC facility.

73. CSCTC also failed to establish a system for monitoring environmental conditions to prevent contamination during aseptic processing, as required by 21 C.F.R. § 211.42(c)(10)(iv). For example, during FDA's 2017 inspections of the CSCTC facilities, Defendants manufactured the SVF and SVF/Vaccinia products in a "surgery" room with no environmental monitoring program. Defendants did not perform any type of surface, air, or personnel monitoring for viable microorganisms, nor any active air monitoring for non-viable particles.

74. CSCTC failed to establish written procedures for production and process control designed to assure the drug products have the identity, strength, quality and purity they purport or are represented to possess, as required by 21 C.F.R. § 211.100(a), because they failed to validate the manufacturing process and perform in-process testing and establish specifications for a safe and effective final product. Specifically, although Defendants Berman and Lander confirmed that CSCTC performs viability and cell count testing on the final SVF product, the testing is performed without any specifications or release criteria, and no other testing was performed. Additionally, Dr. Lander stated that regardless of the SVF testing results, he would still administer the patient's cells back to them.

75. CSCTC failed to establish laboratory controls that include scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity,

strength, quality, and purity, as required by 21 C.F.R. § 211.160(b). For example:

- CSCTC failed to establish specifications/acceptance criteria and did not perform testing on the components used to manufacture their SVF product, including the TMAX enzyme used to process adipose tissue. Although Defendants obtained Certificates of Analysis ("COAs") for the TMAX enzyme, several COAs stated that the product was "For in Vitro Use Only." Defendants, however, were using it in a clinical setting to prepare the CSCTC products.

- Additionally, the Defendants failed to evaluate the impact of freezing/thawing on the TMAX enzyme used in their manufacture of SVF products.

- No testing was performed on ACAM2000 Vaccinia Virus vaccine prior to mixing it with SVF for administration to patients.

- For their Expanded SVF product, there was no documentation showing when the expanded cells were received at CSCTC's Rancho Mirage facility, or the condition of expanded cells upon receipt, or the condition under which the expanded cells were stored. In addition, although Defendants' protocol for frozen or expanded cells states that "a sample should be evaluated on site for gram stain or rapid infection evaluation . . . [or alternatively] sent out for routine culture to validate the maintenance of sterility during transportation as a further validation of the reported laboratory sterility . . . . " Dr. Lander confirmed that such measures were not performed.

J. Defendants' CSCTC products and similar products are associated with adverse events

76. On February 6, 2017, a patient with COPD lost consciousness and was hospitalized after being treated with Defendants' SVF product intravenously and with a nebulizer at CSCTC Beverly Hills. Defendants did not identify the event as an adverse event. Yet Defendants noted in the patient's records that in the future, the patient should only receive intravenous SVF and "NO nebulizer."

77. On April 16, 2016, a patient who received SVF product injected through a catheter into the area around the brain at CSCTC Beverly Hills was hospitalized when testing revealed evidence of infection.

78. On March 21, 2016, a patient who received SVF product in her knee at CSCTC Beverly Hills reported experiencing an infection and being unable to walk for six months.

79. Defendants also received reports of adverse events related to the administration of the CSCTC products by CSN affiliates.

80. Defendants' records show that a patient who received an "SVF surgical procedure" in her eyes from a CSN affiliate on or about September 8, 2016, reported a retinal detachment. Defendants subsequently told affiliates that SVF was no longer to be injected into patients' eyes.

81. Scientific literature documents the harmful effects that may occur as a result of administering cellular products derived from adipose tissue using routes of administration such as those intended for Defendants' SVF product. Those harmful effects include administration site reactions such as swelling, tendonitis, and intra-articular pain, as well as systemic reactions manifested by transient fever, facial flushing and myalgia, and pulmonary embolism.[3]

82. In March 2017, the New England Journal of Medicine ("NEJM") published a report on the three "serious adverse events" involving adipose-derived stromal vascular fraction products similar to those manufactured by the Defendants. See Ajay E. Kuriyan, et al., Vision Loss after Intravitreal Injection of Autologous "Stem Cells" for AMD, 376 NEW ENG. J. MED. 1047, 1050 (Mar. 16, 2017), available at http://www.nejm.org/doi/full/10.1056/NEJMoa1609583#t=article (last accessed: July 3,

[3] *See, e.g.*, Pak J et al, Safety reporting on implantation of autologous adipose tissue-derived stem cells with platelet-rich plasma into human articular joints. BMC, Musculoskelet Disord, 2013;14-337; Siennicka K et al, Adipose-derived cells (stromal vascular fraction) transplanted for orthopedic or neurological purposes: are they safe enough? Stem Cell International, 2016 Article ID 5762916; Lalu MM et al, Safety of cell therapy with mesenchymal stromal cells (SafeCell): a systematic review and meta-analysis of clinical trials. PLoS ONE 2012;7 (10): e47559; Rodriguez JP et al, Autologous stromal vascular fraction therapy for rheumatoid arthritis: rationale and clinical safety. Int Arch Med, 2012, 5:5; Jung JW et al, Familial occurrence of pulmonary embolism after intravenous adipose tissue-derived stem cell therapy. Yonsei Med J, 2013;54: 1239-96; and Tatsumi et al, Tissue factor triggers procoagulation in transplanted mesenchymal stem cells leading to thromboembolism. Biomedical and Biophysical Research Communications 2013, 431; 203-209).

2020). The NEJM report acknowledged that experimentation on patients in this manner could lead to "devastating outcomes." Id. The NEJM report noted that the patients' complications were "probably due to the stem-cell preparations." Id. at 1052.

K. Defendants received prior warnings of their FDCA violations

83. Prior to the July 2017 inspections, Defendants knew that a CSN affiliate had received a Warning Letter from FDA in December 2015 concerning the affiliate's preparation and administration of SVF. The 2015 Warning Letter to the CSN affiliate explained that Defendants' unapproved SVF product was a drug and biological product under the FDCA, and that it was not being lawfully marketed under the FDCA.

84. Both during and following the July 2017 inspections, Defendants asserted to FDA that they did not manufacture drugs or biological products and that they were not subject to the FDCA.

85. In August 2017, United States Marshals seized five vials of ACAM2000 that Defendants used to prepare their SVF/Vaccinia product.[4]

86. Following the seizure, Defendants issued a press release stating that FDA showed "a lack of understanding surrounding autologous surgical procedures" and noted that Defendants had submitted "multiple IDE and IND applications to FDA." As Defendants knew at the time, FDA had never approved any such IDE, nor had any IND ever gone into effect for any of the CSCTC products.

87. During additional communications with FDA in August and October 2017, Defendants reiterated that they were not subject to the FDCA.

88. Defendants have never acknowledged that they have violated the FDCA as to their SVF/Vaccinia product. The Government's seizure of ACAM2000 does not prevent Defendants from trying to obtain ACAM2000 again, or to combine SVF with any other live virus or vaccine.

89. Defendants have never acknowledged that they have violated the FDCA as

[4] *See United States v. Five Articles of Drug, ACAM2000, Vaccinia Vaccine, Live,* 8:17-CV-01449-JVS-(KESx) (C.D. Cal. Mar. 20, 2018), ECF No. 27.

to their Expanded SVF product. This is true even after Defendants' contract manufacturer for the Expanded SVF product received a Warning Letter from FDA and committed to comply with the law. FDA's 2018 Warning letter to the contract manufacturer explained that FDA approvals were required for the Expanded SVF products and identified evidence of significant CGMP violations. The voluntary compliance by Defendants' contract manufacturer does not prevent Defendants from committing or causing similar violations of the FDCA.

L. FDA's Regulation of HCT/Ps under the Public Health Service Act

90. Under the authority of section 361 of the Public Health Service Act ("PHSA"), 42 U.S.C. § 264, FDA established regulations for "human cells, tissues, or cellular or tissue-based products" ("HCT/Ps") to prevent the introduction, transmission, and spread of communicable diseases.[5] These regulations can be found in 21 C.F.R. Part 1271. Thus, the Same Surgical Procedure exception and other regulations in Part 1271 were promulgated pursuant to the PHSA, 42 U.S.C. § 201 *et seq.*, and not the FDCA, 21 U.S.C. § 301 *et seq.*

91. In a March 4, 1997 Federal Register notice (62 Fed. Reg. 9721), FDA announced the availability of a document entitled "Proposed Approach to Regulation of Cellular and Tissue-Based Products (dated February 28, 1997)" ("Proposed Approach").[6] In the Proposed Approach, FDA recognized that in certain circumstances cells or tissues removed and subsequently transplanted during surgical procedures would be excepted from FDA regulation. Proposed Approach at 7. But the Proposed Approach made clear that any exception from FDA regulation would be narrow. For example, "[c]ells and tissues that were manipulated extensively, combined with non-tissue components, or were

[5] HCT/Ps are defined as "articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient." 21 C.F.R. § 1271.3(d).

[6] *See* Proposed Approach, FDA Dkt. No. 97N-0068 (February 1997) https://www.fda.gov/regulatory-information/search-fda-guidance-documents/proposed-approach-regulation-cellular-and-tissue-based-products.

to be used for other than their normal functions would be regulated as biologics or devices requiring premarket approval by FDA." *Id*. at 7; *United States v. US Stem Cell,* 403 F. Supp. 3d 1279, 1291 (S.D. Fla. 2019).

92. The Proposed Approach was not a guidance document. Rather it was described in FDA's Federal Register announcement as a **"**Notification of proposed regulatory approach." The Proposed Approach was akin to an Advance Notice of Proposed Rulemaking[7] in that it gave the public notice of the FDA's early thinking about the regulation of "human cellular and tissue-based products." The Proposed Approach started the process of engaging the public on this topic to inform FDA's drafting of a proposed rule. Accordingly, FDA's Federal Register notice announced that FDA would hold a public meeting to solicit information and views on the Proposed Approach, and further requested the public's written comments so that the agency could "ensure their adequate consideration in preparing FDA's *final approach* to the regulation of cellular and tissue-based products." *Id.* (emphasis added).

93. Subsequently, in the Federal Register of May 14, 1998, FDA published its Proposed Rule Concerning "Establishment Registration and Listing for Manufacturers of Human Cellular and Tissue-Based Products." *See* 63 Fed. Reg. 26744 ("Proposed Rule"). In the preamble to its 1998 Proposed Rule, FDA included a discussion and example that illustrated the narrow scope of the Same Surgical Procedure exception, as then proposed:

> An establishment or person that removes human cellular or tissue-based products from an individual and then implants, transplants, infuses, or transfers those cells or tissues into the same individual is not required to register or list with the agency, so long as the human cellular or tissue based product is quarantined pending completion of the surgery. For

[7] An Advance Notice of Proposed Rulemaking is a preliminary notice, published in the Federal Register, announcing that an agency is considering a regulatory action. The agency issues an ANPRM before it develops a detailed proposed rule. An ANPRM describes the general area that may be subject to regulation and usually asks for public comment on the issues and options being discussed. An ANPRM is issued only when an agency believes it needs to gather more information before proceeding to a notice of proposed rulemaking. See https://www.reginfo.gov/public/jsp/eAgenda/Abbrevs.myjsp.

> example, a surgeon might remove a saphenous vein from a patient for use in a later coronary bypass in the same patient. Registration and listing would not be required unless the saphenous vein was stored with other cellular or tissue-based products.
>
> Proposed Rule, 63 Fed. Reg. at 26748; *see US Stem Cell*, 403 F. Supp. 3d at 1291.

94. On January 19, 2001, through notice and comment rulemaking, FDA issued its Final Rule, which codified the Same Surgical Procedure exception in 21 C.F.R. § 1271.15(b) in the form it exists today.[8] The preamble to the Final Rule clarified, among other things, that "hospitals that store autologous cells or tissues for subsequent application in the same patient" would qualify for the Same Surgical Procedure exception "so long as the hospital does not engage in any other activity encompassed within the definition of 'manufacture'" such as "expand[ing] the cells or tissues." 66 Fed. Reg. 5447, 5460 (Jan. 19, 2001); *see US Stem Cell*, 403 F. Supp. 3d at 1291-92.

95. FDA issued its non-binding interpretation of the limited scope of the Same Surgical Procedure exception long before this case was initiated.[9] The interpretation was explained in several guidance documents, including a Draft Guidance for Industry released in October 2014 ("2014 Draft Guidance")[10] and a Final Guidance issued in November

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[8] Final Rule Concerning Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing ("Final Rule"), 66 Fed. Reg. 5447, 5468 (Jan. 19, 2001).

[9] The Government brought this enforcement action based on the authority, plain meaning, and binding effect of the FDCA, PHSA, and Part 1271 regulations rather than any agency guidance. *See generally* Pl.'s Compl. (ECF No. 1). FDA's Guidances and the Same Surgical Procedure exception's history set forth therein are referenced to establish that deference would be appropriate were this Court to find the exception ambiguous.

[10] *Same Surgical Procedure Exception under 21 CFR 1271.15(b): Questions and Answers Regarding the Scope of the Exception, Draft Guidance for Industry* (Oct. 2014), https://wayback.archiveit.org/7993/20170404000725/https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/UCM419926.pdf.

2017 ("2017 Final Guidance").[11]

96. Consistent with the examples provided during development of the regulation and in the preamble to the Final Rule, FDA's 2014 Draft Guidance provided examples of HCT/P's used in surgical procedures that would be entitled to the Same Surgical Procedure exception, including "autologous skin grafting and coronary artery bypass surgery involving autologous vein or artery grafting." 2014 Draft Guidance at 4. FDA further explained that an establishment that processes an HCT/P after removal and prior to implantation generally would not qualify for the exception.

97. In finalizing the guidance in November 2017, FDA reiterated the exception's narrow reach and the agency's belief that "[g]enerally, the only processing steps that will allow an HCT/P to remain 'such HCT/P' are rinsing, cleansing, sizing, and shaping." 2017 Final Guidance at 5. FDA's 2017 Final Guidance further reiterated that an establishment that processes an autologous HCT/P after removal and prior to implantation generally would not qualify for the Same Surgical Procedure exception. Id. at 7.

98. The 2017 Final Guidance followed a public notice and comment period as well as a two-day public hearing. 79 Fed. Reg. 63348 (Oct. 23, 2014) (announcing a 60-day public comment period). Defendant Lander and other members of the public participated in the hearing. *See* Tr. of Part 15 Hearing: Draft Guidances Relating to the Regulation of Human Cells, Tissues, or Cellular or Tissue-based Products at 148-153 (Sept. 12, 2016).[12]

M. FDA's Enforcement Discretion Policy Does Not Extend to Products That Raise Potential Significant Safety Concerns

99. In 2017, FDA issued a guidance entitled "Regulatory Considerations for

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[11] *Same Surgical Procedure Exception under 21 CFR 1271.15(b): Questions and Answers Regarding the Scope of the Exception* (Nov. 2017), https://www.fda.gov/media/89920/download.

[12] https://www.fda.gov/downloads/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/UCM532350.pdf.

Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use" which clarified FDA's interpretation of certain criteria concerning the regulation of HCT/P's. The guidance explained that FDA generally intended to exercise enforcement discretion with respect to certain premarket approval requirements for a period of 36 months. However, the guidance clarified that such enforcement discretion would only be applied "where use of the HCT/P does not raise reported safety concerns or potential significant safety concerns."

100. The guidance further clarified that focus would be on products with higher risk profiles:

> FDA intends to focus enforcement actions on products with higher risk, including based on the route and site of administration. For example, actions related to products with routes of administration associated with a higher risk (e.g., those administered by intravenous injection or infusion, aerosol inhalation, intraocular injection, or injection or infusion into the central nervous system) will be prioritized over those associated with a lower risk (e.g., those administered by intradermal, subcutaneous, or intra-articular injection).
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> Guidance at 21-22.

Any Finding of Fact which is properly deemed a Conclusion of Law shall be considered a Conclusion of Law.

IV. CONCLUSIONS OF LAW

A. Jurisdiction and Venue Are Established

1. The Court has jurisdiction over the parties and the subject matter of this action pursuant to 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, and 1345.

2. Venue in this district is proper under 28 U.S.C. §§ 1391(b) and (c).

B. Defendants and their CSCTC products are subject to FDA regulation

3. Under the FDCA, a "drug" includes any article that is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," 21 U.S.C. § 321(g)(1)(B), or that is "intended to affect the structure or any function of the body," 21 U.S.C. § 321(g)(1)(C).

4. The CSCTC products are "drugs" within the meaning of the FDCA, 21 U.S.C. § 321(g)(1)(B) and (C), because Defendants' records, public statements, and information contained on Defendants' websites and elsewhere establish that CSCTC products are intended to be used in the cure, mitigation, or treatment of diseases in man and/or to affect the structure and function of the body.

5. The CSCTC products are "prescription drugs" within the meaning of 21 U.S.C. § 353(b)(1)(A) because, due to their toxicity or other potentiality for harmful effect, or the method of their use, or the collateral measures necessary to their use, they are not safe for use except under the supervision of a practitioner licensed by law to administer such drug.

6. The CSCTC products are "new drugs" within the meaning of 21 U.S.C. § 321(p)(1), because they are not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling. The CSCTC products are also "new drugs" within the meaning of 21 U.S.C. § 321(p)(2), because they have not been used to a material extent or for a material time under the conditions prescribed, recommended, or suggested in their labeling.

7. The CSCTC products are "biological products" within the meaning of the Public Health Service Act ("PHSA"), 42 U.S.C. § 262(i).

8. The CSCTC products are "human cells, tissues, or cellular or tissue-based products" ("HCT/Ps"), which are defined as "articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient." 21 C.F.R. § 1271.3(d).

C. Defendants failed to meet their burden to prove that the CSCTC Products meet the regulatory criteria in 21 C.F.R. § 1271.10(a)

9. The CSCTC products do not meet all of the regulatory criteria in 21 C.F.R. § 1271.10(a).

10. The CSCTC products are more than minimally manipulated within the meaning of 21 C.F.R. § 1271.10(a)(1) and § 1271.3(f).

11. The CSCTC products are not "intended for homologous use only" within the meaning of 21 C.F.R. § 1271.10(a)(2) and § 1271.3(c).

12. The SVF/Vaccinia product involves the combination of an HCT/P with "another article" within the meaning of 21 C.F.R. § 1271.10(a)(3).

13. Defendants have not met their burden of establishing that each of the SVF, SVF/Vaccinia and Expanded SVF products meets all of the regulatory criteria in 21 C.F.R. § 1271.10(a). See 21 C.F.R. § 1271.10(a); *United States v. First City Nat'l Bank of Houston*, 386 U.S. 361, 366 (1967) (holding that the general rule is that the burden is carried by the one who "claims the benefit of an exception to the prohibition of a statute"); *FTC v. Morton Salt Co.*, 334 U.S. 37, 44-45 (1948); *Harry C. Crooker & Sons v. Occupational Safety and Health Review Comm'n*, 537 F.3d 79, 85 (1st Cir. 2008).

D. Defendants failed to meet their burden to prove that their establishments qualify for the regulatory exceptions in 21 C.F.R. § 1271.15

14. The CSCTC products do not qualify Defendants' establishment for any of the exceptions in 21 C.F.R. § 1271.15.

15. Defendants remove adipose tissue from their patients and return cells or cell debris derived from that tissue that have been altered during processing.

16. In manufacturing the CSCTC products, Defendants do not implant the HCT/P, i.e., adipose tissue, that was removed from their patients. [13]

[13] The Court instructed the Government to present evidence regarding "whether the SVF Procedure alters the SVF cells" at trial. *See* fn.3, *supra* (citing ECF No. 84 at 13). Even if the Court were to find that the SVF cells (*i.e.* not adipose tissue) are the relevant "HCT/P," for purposes of its section 1271.15(b) analysis, Defendants still do not implant "such HCT/P" that was removed from their patients.

17. Defendants have not met their burden of establishing that the § 1271.15(b) exception to "the requirements of [21 C.F.R. Part 1271]" applies here. See 21 C.F.R. § 1271.15(b); *United States v. Regenerative Scis., LLC*, 741 F.3d 1314, 1322 (D.C. Cir. 2014) (citing *United States v. First City Nat'l Bank of Houston*, 386 U.S. at 366); *FTC v. Morton Salt Co.*, 334 U.S. 37, 44-45 (1948); *Harry C. Crooker & Sons v. Occupational Safety and Health Review Comm'n*, 537 F.3d 79, 85 (1st Cir. 2008).

18. The Same Surgical Procedure exception set forth at 21 C.F.R. §1271.15(b), applies to "an establishment that removes HCT/P's from an individual and implants such HCT/P's into the same individual during the same surgical procedure." Section 1271.15(b) unambiguously describes limited circumstances wherein an establishment can avail itself of the Same Surgical Procedure exception. Applying traditional tools of construction, including the rule that all words be given effect, *First Charter Financial Corp. v. United States*, 669 F.2d 1342, 1350 (9th Cir. 1982), the phrase "such HCT/P's" makes clear that the HCT/P implanted in the patient must be the HCT/P in the form removed from the patient for the exception to apply. Section 1271.15(b) does not apply where, as here, the HCT/P ultimately returned to the patient is plainly different from the HCT/P that was removed. As the court in US Stem Cell recently recognized in a case nearly identical to the present case, "the text of §1271.15(b) unambiguously supports the FDA's interpretation that 'such HCT/P's' refers to the antecedent HCT/P removed from the patient in its original form." *US Stem Cell*, 403 F. Supp. 3d at 1288.

19. Instead of focusing, as required by the plain meaning of the regulation, on the HCT/P in the form removed from their patients (i.e., as adipose tissue), Defendants focus on just part of the removed tissue after processing (i.e., certain cells), and argue that that the Same Surgical Procedure exception applies because specific cells isolated from the processed tissue purportedly remain unaltered. Defendants' expansive interpretation of the narrow Same Surgical Procedure exception would completely swallow the well-established statutory and regulatory rules for any product manufactured from a patient's HCT/P. Under Defendants' interpretation, an establishment could remove any tissue from

any part of a patient, perform any number and type of manufacturing steps on that tissue in relation to any purported surgical procedure (regardless of the risk associated with any of those steps), inject the end product into any part of the patient, and then invoke the Same Surgical Procedure exception as long as the end product contained one or more cells that were present in the original HCT/P—no matter how wildly different in form and function the end product might be. Because Defendants remove adipose tissue from their patients, their interpretation, which focuses solely on returned cells, effectively reads "tissue" out of the regulation.

20. FDA has consistently and reasonably interpreted the Same Surgical Procedure exception set forth at 21 C.F.R.§ 1271.15(b), and Defendants have been provided adequate due process regarding FDA's interpretation.

21. Part 1271 of Title 21 of the Code of Federal Regulations is not ambiguous. But even if it were, in *Kisor v. Wilkie*, 139 S. Ct. 2400 (2019), the Supreme Court explained that courts should defer to an agency's interpretation of an ambiguous regulation where "the character and context of the agency interpretation entitles it to controlling weight." 139 S. Ct. at 2416. To guide that inquiry, courts must look to whether the agency's position represents the agency's actual view, reflects its "fair and considered judgment," is not merely an "ad hoc" statement, does not create "unfair surprise," and implicates the agency's substantive expertise. *Id.* at 2416-18. When deference applies, it "gives an agency significant leeway to say what its own rules mean." *Id.* at 2418. Therefore, even if the relevant regulation here were ambiguous, FDA's view regarding the impact of Defendants' processing of the CSCTC products is entitled to deference. *See Cytori Therapeutics v. FDA*, 715 F.3d 922 (D.C. Cir. 2013); *see also Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512-16 (1994), quoting *Pauley v. BethEnergy Mines, Inc.*, 501 U.S. 680, 697 (1991) (explaining that FDA's interpretation should be accorded substantial deference because its interpretation "necessarily require[s] significant expertise and entail[s] the exercise of judgment grounded in policy concerns.*"); see also United States v. Regenerative Scis., LLC*, 878 F. Supp. 2d 248, 258 (D.D.C. 2012); *Kisor*, 139 S. Ct. at

2417.

E. The CSCTC products are drugs and biological products regulated under the FDCA, including its adulteration and misbranding prohibitions

22. A product may be both a drug and a biological product. *See, e.g., United States v. Regenerative Scis., LLC*, 741 F.3d at 1319 ("Both of these wide-ranging definitions clearly apply to the [appellants' stem cell product], an article derived mainly from human tissue"); *United States v. Loran Med. Sys., Inc.*, 25 F. Supp. 2d 1082, 1084-86 (C.D. Cal. 1997) (cell product made from neonatal rabbit and human fetal cells was a drug and a biological product).

23. The CSCTC products are drugs and biological products under the FDCA and section 351 of the PHSA and are subject to the provisions of the FDCA and the PHSA, including the FDCA's adulteration, misbranding, and premarket approval requirements. 21 C.F.R. § 1271.20.

24. Because Defendants do not manufacture the CSCTC products in a manner that conforms to CGMP, the CSCTC products are adulterated within the meaning of the FDCA, 21 U.S.C. § 351(a)(2)(B).

25. The CSCTC products are misbranded within the meaning of the FDCA, 21 U.S.C. § 352(f)(1), because they are drugs and their labeling fails to bear adequate directions for use, and because they are not exempt from the requirements of 21 U.S.C. § 352(f)(1).

26. The CSCTC products are misbranded within the meaning of the FDCA, 21 U.S.C. § 353(b)(4) because they are prescription drugs and, at times prior to dispensing, their labels fail to bear, at a minimum, the symbol "Rx only."

27. Defendants' SVF/Vaccinia product is misbranded within the meaning of the FDCA, 21 U.S.C. § 352(j), because it is "dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof."

F. Defendants and their adulterated and misbranded CSCTC products violate the FDCA

28. Section 331(k) prohibits taking any action with respect to a drug "if such act is done while such article is held for sale . . . after shipment in interstate commerce and results in such article being adulterated or misbranded." 21 U.S.C. § 331(k). A product is "held for sale" if it is used for any purpose other than personal consumption. *United States v. Kaplan*, 836 F.3d 1199, 1209 (9th Cir. 2016) (holding that a physician's use of a medical device on a patient is covered by the FDCA phrase "held for sale"); *United States v. Regenerative Scis., LLC*, 741 F.3d at 1320 (D.C. Cir. 2014) (rejecting a narrow reading of 21 U.S.C. § 331(k), as at odds with "a statutory scheme designed to regulate the safety of drugs at every stage of their distribution"); *United States v. Torigian Labs., Inc.*, 577 F. Supp. 1514, 1521 (E.D.N.Y. 1984), *aff'd*, 751 F.2d 373 (2d Cir. 1984) (unpublished table decision); *see United States v. Diapulse Corp. of Am.*, 514 F.2d 1097, 1098 (2d Cir. 1975); *United States v. Evers*, 643 F.2d 1043, 1050 (5th Cir. 1981) ("A practicing physician may also fall within the bounds of this section. . . . Doctors holding drugs for use in their practice are clearly one part of the distribution process, and doctors may therefore hold drugs for sale within the meaning of [21 U.S.C. § 331(k)]."); *US Stem Cell*, 403 F. Supp. 3d at 1298 n.11.

29. Defendants' CSCTC products are "held for sale" by Defendants because they market and offer their products to patients for commercial purposes other than Defendants' own personal consumption.

30. Defendants' CSCTC products are also held for sale after shipment of one or more of their components in interstate commerce. Defendants' CSCTC products satisfy section 331(k)'s "after shipment in interstate commerce" requirement because at least one component of the CSCTC products (e.g., 0.9% Sodium Chloride Injection, USP) has traveled in interstate commerce. The FDCA defines "drug" to include components of a drug. 21 U.S.C. § 321(g)(1)(D). Courts consistently have interpreted sections 331(k) and 321(g)(1)(D) to mean that the final drug product (here, the CSCTC products) need not

have been shipped in interstate commerce in completed form to satisfy the requirement. *See, e.g.*, *Baker v. United States*, 932 F.2d 813, 814-15 (9th Cir. 1991) ("the 'shipment in interstate commerce' requirement is satisfied even when only an ingredient is transported interstate"*); United States v. Dianovin Pharms., Inc.*, 475 F.2d 100, 103 (1st Cir. 1973) ("appellants' use of components shipped in interstate commerce to make vitamin K for injection brought their activities within section 331(k), and conferred jurisdiction to restrain violations thereof upon the district court"); *Regenerative Scis.*, 741 F.3d at 1320-21; *US Stem Cell*, 403 F. Supp. 3d at 1298 n.11. When one of a drug's components has been shipped in interstate commerce, using that component to manufacture an article of drug that is or becomes adulterated or misbranded violates 21 U.S.C. § 331(k). *Dianovin Pharms.*, 475 F.2d at 103.

31. Components received from outside of California that Defendants use in the preparation and administration of the CSCTC products include 0.9% Sodium Chloride Injection, USP and 5% Dextrose in Lactated Ringer's Injection, both of which originate outside the State. Defendants' manufacturing process also involves an enzyme mixture product (that degrades collagen, among other proteins) made in Indiana. Vaccinia Vaccine used to manufacture the SVF/Vaccinia product was shipped in interstate commerce from Georgia. And their Expanded SVF product comes from a firm outside of California. Further, as a general matter, Congress has specified that "the connection with interstate commerce required for jurisdiction" in "any action to enforce the requirements of [the FDCA] respecting a . . . drug . . . shall be presumed to exist." 21 U.S.C. § 379a; *see United States v. Chung's Prods. LP*, 941 F. Supp. 2d 770, 795 (S.D. Tex. 2013).

32. Defendants violate 21 U.S.C. § 331(k) by causing the adulteration of CSCTC products within the meaning of 21 U.S.C. § 351(a)(2)(B), while they are held for sale after shipment of one or more of their components in interstate commerce.

33. Defendants violate 21 U.S.C. § 331(k) by causing the misbranding of CSCTC products within the meaning of 21 U.S.C. §§ 352(f)(1), 352(j), and 353(b)(4), while they are held for sale after shipment of one or more of their components in interstate commerce.

34. Defendants CSCTC, Berman, and Lander violate 21 U.S.C. § 331(c) by receiving drugs that are misbranded within the meaning of 21 U.S.C. §§ 352(f)(1) and 353(b)(4) in interstate commerce and delivering or proffering for delivery such drugs for pay or otherwise.

35. Defendants claim that the FDCA does not apply to them because they are simply physicians who are practicing medicine and performing surgery. However, even doctors must comply with FDCA requirements. The FDCA "enacts a comprehensive, uniform regulatory scheme for the distribution of drugs." *Regenerative Scis*, 741 F.3d at 1319-20. Although the FDCA contains some exceptions that apply to physicians, Congress did not create a broad "practice of medicine" exception that allows physicians to do whatever they please. *Id*.; *see also United States v. Evers*, 643 F.2d 1043, 1048 (5th Cir. 1981) ("[W]hile the [FDCA] was not intended to regulate the practice of medicine, it was obviously intended to control the availability of drugs for prescribing by physicians."); *see also US Stem Cell*, 403 F. Supp. 3d at 1300 n.12. Moreover, although Defendants claim they merely engage in "off-label uses" of medical products, that argument fails because the CSCTC products have not been approved by FDA for *any* use. *See Regenerative Scis.*, 741 F.3d at 1324-25 (appellant doctors' prescription of unapproved stem cell "Mixture" not entitled to categorical exemption from FDA labeling requirements).

G. Defendants' purported affirmative defense lacks merit and does not excuse their FDCA violations

36. Allegations that an agency acted arbitrarily or capriciously may be brought, under certain circumstances not present here, pursuant to the Administrative Procedure Act ("APA"). *See, e.g.*, 5 U.S.C. § 706. However, the limited waiver of sovereign immunity under the APA is a cause of action—not an affirmative defense. *See generally* 5 U.S.C. § 702 (providing an independent cause of action for judicial review of final agency action).

37. In any event, FDA's decisions to take enforcement action are "not subject to

judicial review under the APA." *See Heckler v. Chaney*, 470 U.S. 821, 838 (1985). Under its enforcement power, FDA has absolute discretion on whether to bring an enforcement action. *Id.* at 831. Here, FDA's exercise of discretion is valid because it is not based on an unjustifiable standard such as "race, religion, or other arbitrary classification." *See, e.g., Bordenkircher v. Hayes*, 434 U.S. 357, 364 (1978). FDA has also treated similarly situated parties in the same manner as it has treated Defendants. *See, e.g., United States v. U.S. Stem Cell Clinic*, 403 F. Supp. 3d 1279.

38. There is no due process violation where an agency acts and provides for an adequate opportunity for the petitioner to be heard. *See Mathews v. Eldridge*, 424 U.S. 319, 349 (1976). Additionally, due process is not prescriptive in its requirements. FDA's formal notice-and-comment rulemaking process, iterative guidance, Federal Register notices concerning FDA's rulemaking and guidance, and attendant opportunities for notice, hearing, and comment have provided sufficient opportunity for Defendants to be heard regarding FDA's interpretation of the Same Surgical Procedure exception. *See Pinnacle Armor, Inc. v. United States*, 648, 717 (9th Cir. 2011) ("All that is required before a deprivation of a protected interest is notice and opportunity for hearing appropriate to the nature of the case.") (internal quotations omitted).

39. Moreover, inadequate notice cannot be pleaded where not only is actual notice not required but Defendants had actual notice regarding FDA's interpretation in fact. *See Foss v. Nat'l Marine Fisheries Services, 161 F.3d 584, 589-90* (9th Cir. 1998); *see also Lyng v. Payne*, 476 U.S. 926, 942-43 (1986).

40. Substantive due process claims must fail where the government's actions have a substantial relation to the public health, safety, or well-being. *Euclid v. Ambler Realty Co.*, 272 U.S. 365, 395 (1926); *Kim v. United States*, 121 F.3d 1269, 1273-74 (9th Cir. 1997); *Dodd V. Hood River County*, 59 F.3d 852, 864 (9th Cir. 1995) ("There is no denial of substantive due process if the question as to whether the government acted arbitrarily or capriciously is at least debatable.") (internal quotations omitted).

41. Defendants' additional argument that patients have a constitutional right to

control their tissues and cells also fails. There is simply no constitutional right to receive unapproved products regulated by the FDA. *See United States v. Rutherford*, 442 U.S. 544, 552 (1979) (terminally ill patients do not have a constitutional right to obtain the unapproved drug Laetrile); *Abigail Alliance v. von Eschenbach*, 495 F.3d 695, 711 (D.C. Cir. 2007) (terminally ill patients have no constitutional right to unapproved experimental drugs).

H. The Government is entitled to a statutory injunction to enjoin Defendants' FDCA violations and protect the public health

42. Under 21 U.S.C. § 332(a), district courts have jurisdiction to enjoin violations of the FDCA. *United States v. Organic Pastures Dairy Co.*, 708 F. Supp. 2d 1005, 1011 (E.D. Cal. 2010); *United States v. Innovative Biodefense, Inc.*, 2019 WL 2428672, at *3 (C.D. Cal. June 5, 2019). The FDCA's injunctive power should be exercised in light of its purpose to protect the public health, *see United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 798 (1969), and is appropriate when the United States establishes that the defendant has violated the applicable statute and that there exists "some cognizable danger of recurrent violation." *United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953); *United States v. Rhody Dairy*, 812 F. Supp.2d 1239, 1245-46 (W.D. Wash. 2011).

43. The probability of future violations may be inferred from past unlawful conduct. *See United States v. Laerdal Mfg. Corp.*, 73 F.3d 852, 857 (9th Cir. 1995) (citing *S.E.C. v. Koracorp Indus., Inc.*, 575 F.2d 692, 698 (9th Cir. 1978)); *United States v. Odessa Union Warehouse Coop*, 833 F.2d 172, 176 (9th Cir. 1987); *Organic Pastures*, 708 F. Supp. 2d at 1012.

44. Defendants argue that injunctive relief is inappropriate because they are not currently manufacturing certain products and have "no interest" in manufacturing them without appropriate FDA approvals. However, it is well-established that the "the court's power to grant injunctive relief survives discontinuance of the illegal conduct." *United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953); *see also United States v. Odessa Union Warehouse Co-op*, 833 F.2d 172, 176 (9th Cir. 1987). "[M]ere cessation of violative

activities is not, of itself, grounds for denial of a statutory injunction sought to protect the public health. This is particularly true where such cessation arises only as a result of . . . threatened litigation." *United States v. Sene X Eleemosynary Corp. Inc.*, 479 F. Supp. 970, 981 (S.D. Fla. 1979) (internal citation omitted).

45. Plaintiff, the United States of America, is entitled to a statutory injunction to protect the public health because the evidence shows that Defendants have repeatedly violated *(a)* 21 U.S.C. § 331(k) by causing the adulteration and misbranding of drugs while holding them for sale after shipment of one or more of their components in interstate commerce, and *(b)* 21 U.S.C. § 331(c), by receiving misbranded drugs in interstate commerce and delivering or proffering for delivery such drugs for pay or otherwise. Based on these repeated violations, there is a reasonable expectation that Defendants will continue to violate the FDCA in the future if not enjoined.

Any Conclusion of Law which is properly deemed a Finding of Fact shall be considered a Finding of Fact.

DATED: _____

_____
HONORABLE JESUS G. BERNAL
United States District Judge

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